Maximising quality for pharmaceutical products

According to Jørgen Læssøe, glass tube manufacturers serving the pharmaceutical industry can achieve improved market share by using the best available inspection systems.

Glass tubes are used widely for pharmaceutical products, because glass provides excellent containment, as well as allowing the user to have the final check of contents.

Recently, considerable attention has been paid to the quality of glass containers used for pharmaceuticals. The Food and Drug Administration has demanded improved quality, while the Parenteral Drug Association has published a guide to the inspection of glass containers (PDA Technical Report 43).

Defects found in this type of glass packaging include stone, knots, cracks and chips. To produce vials and syringes, good quality glass tubing is required. Many of the defects can be found at the drawing line, where sections of tubes with defects can be discarded, just after the rough cut.

Standard inspection equipment used today includes the JLI SK 3000, capable of finding stone and knots down to 50µm, at speeds of up to 10m/second. Airlines with a diameter of 20µm and a length of 2mm can also be detected. In a typical production situation, 20% of tubes are rejected. Because it is not easy to eliminate defects in the process, sorting is the accepted way to achieve a certain quality level.

Final inspection of filled syringes.

As demand for tubes with smaller defects increases, JLI was approached to develop the next generation tube inspector, with a sensitivity four times better than the standard SK 3010 equipment. This system is called SK 4010 D and will be launched in the second quarter of 2012.

The SK 4010 D will find defects down to 15µm and airlines down to 5µm diameter, with lengths of just 1mm. The inspection speed is raised to 15m/second, depending on configuration. This is achieved by adding cameras, which means that eight cameras are used compared to the three used in SK 3000 equipment. The cameras also have higher resolution and the latest optics increase the magnification. To obtain sharp images, the tube must be transported through the system with an accuracy of +/- 3mm. The extra cameras and higher picture frequency necessitate data processing speeds of up to 500 Megapixels/second. This is achieved by using two industrial computers, equipped with quadruple CPUs.

With this system, detection capabilities are improved by a factor of four on all defects. If tube production is sorted with four-times sharper defect detection, reject rates may increase to 50% or more. This may seem unacceptable but when looking at the costs caused by defects going through the many processes to final product, it is not significant.

JLI also develops inspection systems for the pharmaceutical industry and knows the kind of defects which are regarded as critical in the final product. In the pharmaceutical industry, inspection is performed immediately prior to packaging. Cracks may cause water in medicines to evaporate slowly and thereby, the medicine will have a higher concentration. Contamination of the sterile contents is also an issue.

At final inspection just before packaging, the product may cost several hundred Euros. Discarding the container with the medicine at this point is, of course, very expensive. In comparison, the cost of the glass tube is insignificant.

Defects found during final inspection are mostly cracks. These come from a combination of temperature and mechanical stress associated with imperfections in the raw glass tube.

Therefore, it is anticipated that the drive for high quality (zero defects) will justify a price of the raw tube that could be many times higher than the price of tubes currently produced.

With this perspective, it makes sense for glass tube producers to discard half of their production to gain a much higher quality and thereby, a higher price.

In the glass tube production sector today, some tubes have zero defects and they can be sold at a higher price. The latest tube inspection system can grade each section of tube in standard quality and high quality. Using this grading method, reject rates will not be increased, although the best tubes will be diverted after the rough cut and can be sold at a much higher price.

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